K011836

SEP - 7 2001

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:

PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121
Tel: 858-550-3800 – Fax: 858-550-3813
Attn: Mr. Hartmut Loch, RAC
Director, Regulatory Affairs

Trade name: MPF Acetabular Cup

Common name: Acetabular Cup

Classification name: Hip joint metal/polymer semi-constrained uncemented prosthesis.
§ 888.3353, Class II, Orthopedic Device Panel 87

Product Code: LZO & LWJ

Device Description and Characteristics: The MPF Acetabular Cup is a cementless, press-fit cup. It is available in 10 sizes ranging from 46 mm to 64 mm in 2 mm increments. It is manufactured from CP Titanium according to ASTM F 67. UHMWPE inserts are available in neutral and 20° hooded versions. Cancellous bone screws made from Ti6Al4V are available in 7 sizes ranging from 20 mm to 50 mm in length. They have a standard 6.5 mm thread diameter and 3.5 mm octagonal screw head. The cup has 3 screw holes for optional acetabular screw fixation. The open, unused screw holes can be closed with threaded screw hole covers. The MPF cup may be used with the following ball heads manufactured by PLUS and INTRAPLANT that are cleared for marketing by the U.S. FDA:
CS-PLUS® Stem with CoCrMo Ball Head (K936214 - 6/15/94)
SL/SLR-PLUS® Stem with CoCrMo Ball Head (K932481 - 6/8/94)
SL/SLR-PLUS® Stem with Biolox Ceramic Head (K930963 - 1/7/94)
INTRAPLANT Ceramic Ball Heads (K990261 - 8/27/99)
MODULAR-PLUS® Revision Stem (K994126 - 5/4/00)
PLUS CoCrMo Ball Heads (K001942 - 7/25/00)

Equivalence: The MPF Acetabular Cup is substantially equivalent to the LPC-PLUS Acetabular Cup (K003274 – S/E 4/6/2001). Both cups are similar in design. They both are manufactured from CP Titanium conforming to ASTM F67 and are Ti-Plasma coated. In addition, both cups are for uncemented use and are intended for the same medical indications.

Indications: The MPF Acetabular Cup is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions.

Performance data: Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2001

Mr. Helmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, California 92121

Re: K011836
Trade/Device Name: MPF Acetabular Cup
Regulation Number: 888.3353
Regulation Name: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Regulatory Class: II
Product Code: LZO, LWJ
Dated: June 8, 2001
Received: June 12, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K011836

Device Name(s):

MPF ACETABULAR CUP

Indications for Use:

The MPF Acetabular Cup is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011836

Prescription Use ✓ OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)